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safety... our priority.*

*Votre santé et votre
sécurité... notre priorité.*

Health Canada's role in ICATM

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Health Canada**

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Canada

Canada and ICATM

- In 2007, Canada was invited to join the three validation organizations (ICCVAM, ECVAM, and JaCVAM) in a cooperative approach to validating alternative test methods and reaching consensus on recommending their suitability for use
- Canada has no Centre for Validation but
- Canada has contributed expertise to various stages of the validation process and test guideline development
- Primary interest is in ensuring that new alternative methods or strategies offer equivalent or better protection of human health while respecting the 3Rs
- The Environmental Health Science and Research Bureau continues to coordinate Canada's input



Health Canada

- Health Canada is made up of 12 Branches, Offices and Bureaux as well as 4 Agencies
- Branches involved in regulation of potentially harmful exposures include:
 - **Healthy Environments and Consumer Safety Branch**
 - **Health Products and Food Branch**
 - Pest Management Regulatory Agency
- Relevant instruments include:
 - Acts
 - Regulations
 - Guidelines and standards



Health Canada and Validation

- Although there is no formal programme or VAM, Canada contributes to:
 - Pre-validation research
 - *In vitro* transgenic gene mutation
 - In house research on introducing metabolic activation into *in vitro* assays using transfection methodology
 - Validation lab-work including international collaborative studies
 - Metal bioavailability/bioaccessibility, IPCS studies
 - Validation management committees
 - OECD VMG – Mammalian Methods, E.D.T.A
 - OECD VMG Non-Animal – *in vitro* endocrine disrupters
 - Peer review
 - Independent Scientific Peer review: Use of *In Vitro* Methods for Estimating Starting Doses for Acute Oral Systemic Toxicity Tests – ICCVAM – 2006
 - Lead bioavailability



Health Canada and Method Development/Refinement/Validation

- Activities have been organized through
 - The OECD / International Programme on Chemical Safety
 - The International Workshop on Genotoxicity Testing
 - ICCVAM: future involvement with input to "Interagency Biologics Working Group"
 - Japanese Environmental Mutagen Society
 - Collaboration with "TOXCAST" on mechanisms of action
- Potency and Safety Testing of Biological Products at Health Canada
 - Development and evaluation of alternative assays to the mouse safety test for residual pertussis toxin in vaccines
 - Development of alternative methods for testing of human biotherapeutics e.g. erythropoietin (epo) & collaboration with other regulatory authorities, peer-review publication
- Food Microbiological Safety at Health Canada
 - Via industry-government collaborations (e.g., to evaluate and validate *in vitro* botulinum toxin detection assays in food and biologics)



Update: Health Canada's Role in ICATM

- Health Canada aims to continue to contribute expertise to the validation of alternative tests
- In August 2011, Health Canada will host an ICATM Meeting in Montreal, Quebec (Agenda being finalized)
- Where there are opportunities to participate and adequate resources, we will contribute to:
 - Validation management (design)
 - Validation studies
 - Peer review
 - Recommendations on suitability and limitations for alternative test method use
- Much of this will be accomplished through review of documents



Health Canada

THANK YOU



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